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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,502	04/08/2008	Michele Coati	7202-124 (194359)	9945
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AKERMAN SENTERFITTT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188			EXAMINER CUMBERLEDGE, JERRY	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 10/28/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip@akerman.com

Office Action Summary**Application No.**

10/599,502

Applicant(s)

COATI ET AL.

Examiner

JERRY CUMBERLEDGE

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-19, 24 and 38-40 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) 19, 24 and 38-40 is/are allowed.
- 7) ☒ Claim(s) 1-17 is/are rejected.
- 8) ☐ Claim(s) 18 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 08 August 2011 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bramlet (US Pat. 6,488,684 B2) in view of Biedermann et al. (US Pat. 2005/0187555 A1).

Bramlet discloses an intramedullary nail suitable for insertion in a fractured elongate bone (Fig. 3B) comprising a stem (Fig. 3B, ref. 1) extending between a proximal end and a distal end (Fig. 3B), a plurality of elements (Fig. 3B)(Fig. 6A, refs. S and 16), and a plurality of seats (Fig. 4A, ref. 5) formed in the stem for housing said shape-memory elements (Fig. 3B) and wherein said shape-memory elements are suitable to assume a first configuration of rest in which said shape-memory elements are arranged inside the respective seats and a second configuration of use in which said shape-memory elements project from the nail (Fig. 3B), wherein said shape-memory elements are structurally independent from the stem (Fig. 3B)(Fig. 4A, e.g. they are not monolithic with the stem), and wherein the stem comprises at least two half-cylinders that are axially united (Fig 4A, e.g. left and right halves are united along the longitudinal axis). The seats of the stem consist of a plurality of transversal slots (Fig. 4A, ref. 5), or elongate holes, which extends from one side of the stem to the other side

of the stem (Fig. 4A, ref. 5). The nail comprises inserts (Fig. 4A, ref. 2) comprising at least one of said shape-memory elements (Fig. 4B)(Fig. 6A, refs. 16 and S). Each insert is inserted by pressure in the respective seat (Fig. 3B), as some pressure will be required to force the insert into the seat. Each of said inserts comprises two elements (Fig. 3B, ref. S and 16), which are connected by means of a central connection element (Fig. 6A, ref. 15). Each insert has a substantially fork-like shape (Fig. 6A). Each fork-like insert is suitable to be housed in a corresponding transversal slot (Fig. 3B), in such a manner that the two elements project from opposite sides of the stem (Fig. 3B). The inserts are flanked in succession along the length of the stem (Fig. 3B). The inserts are distributed on the side surface of stem in correspondence with the proximal end and the distal end (Fig. 3B). The inserts are offset with respect to each other by 90 degrees (Fig. 3B, inserts each have four elements which are arranged at 90 degree intervals). The two shape-memory elements of each insert comprise two opposite tabs having a flexural memory (Fig. 6A, ref. 16, S). Each insert is multilaminar having a plurality of overlapped foils of shape-memory material (e.g. elements overlap each other, as they are found around the circumference of the device). The two shape-memory elements of the insert are connected by means of a cylindrical sleeve (Fig. 6A, ref. 15). Two opposite grooves are provided on said cylindrical sleeve, said two opposite grooves being offset by substantially 90 degrees with respect to said two shape-memory elements (Fig. 6A, two grooves formed between refs. 16 and S). The tabs face outwards from the stem (Fig. 6A) and have a substantially sawtooth-like profile (Fig. 6A, ends of refs. 16 and S are tooth-like, as they are pointed)

Bramlet discloses an intramedullary nail suitable for insertion in a fractured elongate bone (Fig. 3B), comprising a stem (Fig. 3B, ref. 1) extending between a proximal end and a distal end (Fig. 3B), a plurality of elements (Fig. 3B)(Fig. 6A, refs. S and 16), and a plurality of seats (Fig. 4A, ref. 5) formed in the stem for housing said shape-memory elements (Fig. 3B), wherein said shape-memory elements are suitable to assume a first rest configuration in which said shape-memory elements are arranged inside the respective seats and a second use configuration in which said shape-memory elements project from the respective seats (Fig. 3B), wherein the nail includes inserts (Fig. 3B, ref. 2), structurally independent from the stem (Fig. 3B, as they are not monolithic with the stem) and comprising at least one of said shape-memory elements (Fig. 3B), each of said inserts being suitable to be arranged in a corresponding seat (Fig. 3B), and wherein each insert is made of a plurality of overlapped metallic foils stacked onto each other and consisting of shape-memory material. Each insert has a substantially fork-like shape (Fig. 6A).

Bramlet et al. disclose the claimed invention except for the elements comprising a shape-memory material.

Biedermann et al. disclose an intramedullary nail suitable for insertion in a fractured elongate bone (Fig. 9a)(Fig. 9b) comprising a stem (Fig. 9a, ref. 60) extending between a proximal end (Fig. 9a, closer to ref. 2) and a distal end of the nail (Fig. 9a, closer to ref. 3) comprising a plurality of elements (Fig. 9a, ref. 70) comprising at least a shape-memory material (paragraph 0052), a plurality of seats formed in the stem for housing said elements (Fig. 9a, ref. 80) and in that said elements are suitable to take a

first shape wherein they are retractably housed in the respective seats (Fig. 9a) and a second shape wherein they project from the respective seats (Fig. 9b). The higher elasticity of the shape-memory barb elements simplifies the handling and provides additional security in anchoring the bone anchoring element in the bone (paragraph 0052).

It would have been obvious to a person having ordinary skill in the art to have constructed to have constructed the elements of Bramlet et al. from a shape-memory material as taught by Biedermann et al., in order to simplify the handling and provide additional security in anchoring the bone anchoring element in the bone (paragraph 0052).

Regarding claim 16 and the phrase "each insert is made of a plurality of overlapped metallic foils stacked onto each other and consisting of shape-memory material" the examiner notes that he is treating this as a product-by-process limitation. It is noted that the device of Bramlet appears to be substantially identical to the device claimed, although possibly produce by a different process (*i.e.* not by a lamination process), therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Response to Arguments

Applicant's arguments filed 08/08/2011 have been fully considered but they are not persuasive.

Regarding Applicant's argument that the elements of Bramlet are not structurally independent from the stem, the examiner notes that he is considering the "stem" of the Bramlet device to be ref. 1 of Fig. 3B and the elements of Bramlet to be refs. S and 16 of Fig. 6A. These component are not directly connected (*i.e.* are not monolithic with one another) and as such may be considered to be "structurally independent" of one another.

Allowable Subject Matter

Claims 19, 24, and 38-40 are allowed.

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-13461346. The examiner can normally be reached on Monday-Friday from 10:00AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, EDUARDO ROBERT, at (571) 272-4719.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733